NOV 5 2002

Attachment 4

K023586

510(k) Summary

Prepared: October 19, 2002

Submitter:

Company Name:	Canon U.S.A., Inc. (U.S. agent/official correspondent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
Fax number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-11 DR-ER add. version
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-11
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	K981556

Description Of Device:

The Canon X-ray digital camera model CXDI-11 DR-ER add. version is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon X-ray Digital Camera CXDI-11 DR-ER add. version is substantially equivalent to the Canon X-ray Digital Camera CXDI-11.

Intended Use:

Canon X-ray digital camera CXDI-11/ CXDI-11 DR-ER add. version provide digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

510(k) Summary

Prepared: October 19, 2002

Submitter:

Company Name:	Canon U.S.A., Inc. (U.S. agent/official correspondent for Canon Inc.)
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Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
Fax number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-22 DR-ER add. version
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-22
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	K992547

Description Of Device:

The Canon X-ray digital camera model CXDI-22 DR-ER add. version is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon X-ray Digital Camera CXDI-22 DR-ER add. version is substantially equivalent to the Canon X-ray Digital Camera CXDI-22.

Intended Use:

Canon X-ray digital camera CXDI-22/ CXDI-22 DR-ER add. version provide digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

510(k) Summary

Prepared: October 19, 2002

Submitter:

Company Name:	Canon U.S.A., Inc. (U.S. agent/official correspondent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
Fax number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-31 DR-ER add. version
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-31
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k)#:	K003689

Description Of Device:

The Canon X-ray digital camera model CXDI-31 DR-ER add. version is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon X-ray Digital Camera CXDI-31 DR-ER add. version is substantially equivalent to the Canon X-ray Digital Camera CXDI-31.

Intended Use:

Canon X-ray digital camera CXDI-31/ CXDI-31 DR-ER add. version provide digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 2002

Ms. Sheila Driscoll
Senior Product Safety Engineer
Canon U.S.A., Inc.
One Canon Plaza
LAKE SUCCESS, NY 11042-1198

Re: K023586
Trade/Device Name: DR-ER Version of Canon X-ray Digital Cameras
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: October 23, 2002
Received: October 25, 2002

Dear Ms. Driscoll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number
(if known) K023586

Device Name

DR-ER Version of Canon X-ray Digital Cameras

Indications for Use

The DR-ER version of Canon's X-ray Digital Cameras provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David A. Lehmann
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023586